



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,160	03/13/2002	Alexander Kozak	800.1015	2914

23280 7590 06/30/2003

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK, NY 10018

EXAMINER

FORD, JOHN M

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 06/30/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/08960

Applicant(s)

Kozak et al

Examiner

J. M. Ford

Group Art Unit

1624

— The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-16 and 18-30 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-16 and 18-30 are subject to restriction or election requirement

Application Papers

- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
- ☐ All ☐ Some* ☐ None of the:
 - ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Art Unit: 1624

The claims in the application are claims 1—16 and 18—30.

This is a 371 of PCT/IL00/00562, filed Sept 13, 2000, should appear as the first line of the specification after the title,

The claims in the application are claims 1—13 and 16—23.

Claim 1 includes multiple different compounds that are patentably distinct in the A variations.

This is a 371 application. Lack of unity of invention in 371 applications is controlled in the United States by 37 CFR 1.475.

37 CFR 1.475 provides for examination of the first named compound invention, one process of making those compounds, and one process of using those compounds.

However, rather than have the Examiner decide what is the invention in claim 1 applicants would have examined here, applicants are given the opportunity to elect which anti-proliferative drug they would have examined in this application; mTX or fluoridene, or whatever else *applicants can support*.

Therefore, restriction is required to one of the following inventions, consistent with PCT Rule 13.2.

- (I) Claims 1—11 drawn to various prodrugs classified variously dependent on what the anti-proliferative drug is. If this group is elected, a further election of a specific drug; *mTX, Fluorouridine* or what ever else applicants can find support, is required.
- (II) Claims 12, and 14-16 are drawn to pharmaceutical composition that will be examined with which ever, *mTX*, etc, is elected in claim 1.


Art Unit: 1624

- (III) Claim 13 drawn to the compounds of claim 1, plus an additional active ingredient. The agreement to ~~examine~~ one method of use with the elected compound invention is ~~based on the~~ ^{an} being of the same scope. Obviously, a claim with an additional active ingredient is of a different scope.
- (IV) Claims 18-29 drawn to multiple methods of using the above compounds. One method of using the compound will be examined with which ever compound is elected. A specific disease is required to be elected, see Rule 475. One method of use.
- (V) Claim 30 drawn to the process of actually making the composition; old and known since the time of Alchemists working in caves.

These compounds have acquired separate status in the art, and will support separate patents. Restriction, as noted, is considered proper. Applicants would not accept a reference for one ring system (mtx, fluorodeoxyuridine, etc) being a reference for any of the other(s).

Applicants response must provide an election, to be considered responsive; 37 CFR 1.499.

Ford/tgd
June 26, 2003


JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624